510(k) Summary MRSA/SA ELITe MGB®

JUN - 1 2012

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: K112937

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Date of Preparation September 29, 2011

Device:

Trade/proprietary Name:	**MRSA/SA ELITe MGB®**
Common or Usual Name:	Test Kit for the detection of methicillin-resistant *Staphylococcus aureus*
Regulation number/name:	866.1640, Antimicrobial susceptibility test powder
Device Class:	Class II
Product code	NQX
Classification name	System, nucleic acid amplification test, dna, methicillin resistant staphylococcus aureus, direct specimen
Classification Advisory Committee:	Microbiology
Panel:	83

Predicate device BD GENEOHM MRSA ACP ASSAY (K093346)

Device description: MRSA/SA ELITe MGB is a real-time, multiplex polymerase chain reaction (PCR) assay for the in vitro qualitative detection of MRSA and SA DNA extracted from human nasal swab samples. In this system, sample preparation and amplification/real-time detection are completed on separate instruments. Sample processing is completed on the bioMérieux NucliSENS® easyMAG® instrument with bioMérieux NucliSENS Nucleic Acid Extraction Reagents according to the manufacturer's instructions. Following processing, the extracted sample is placed in the well of a 96 well plate to which "monoreagent" is added. The monoreagent contains the primers and probes for the genes of interest and the internal control combined with master mix. The assay is performed on an Applied Biosystems 7500 FAST Dx System that consists of the 7500 FAST Dx instrument, a personal computer, 96-well plates and seals. The total system run time is 150 minutes consisting of 60 minutes for sample processing and about 90 minutes for the real time amplification and detection steps. The instrument never comes into contact with any fluids within the 96-well plate. Each disposable plate is intended to test up to 96 samples, controls or any mixture thereof. The 96-well plates are not re-usable and are specific to the system. The kit contains enough reagents for 100 reactions. One positive and one negative control are required for each PCR run ; a Negative

Processing Control and a Positive Processing Control are recommended to be run in each extraction run. The design of the assay includes systems to identify both the gene responsible for methicillin resistance and for a conserved portion of a gene unique to *S. aureus.* Thus, for a true "MRSA," both targets will be identified in roughly equal proportions. Results are determined by using an algorithm that compares output, Cq, from the cycler (called Ct in the output from the cycler.)

Intended Use:

MRSA/SA ELITe MGB® is a qualitative in vitro diagnostic test for the direct detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) using DNA purified from nasal swabs. MRSA/SA ELITe MGB® is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose, guide or monitor MRSA infections, or provide results of susceptibility to oxacillin/methicillin. A negative result does not preclude MRSA/SA (*Staphylococcus aureus*) nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

Indication for use:

MRSA/SA ELITe MGB® is a qualitative in vitro diagnostic test for the direct detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) using DNA purified from nasal swabs. MRSA/SA ELITe MGB® is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose, guide or monitor MRSA infections, or provide results of susceptibility to oxacillin/methicillin. A negative result does not preclude MRSA/SA (*Staphylococcus aureus)* nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

Comparison to Predicate device

	ELITech Molecular Diagnostics Device MRSA/SA ELITe MBG®	Predicate device BD GENEOHM MRSA ACP ASSAY (K093346)
Intended use	MRSA/SA ELITe MGB® is a qualitative in vitro diagnostic test for the direct detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) using DNA purified from nasal swabs. MRSA/SA ELITe MGB® is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose, guide or monitor MRSA infections, or provide results of susceptibility to oxacillin/methicillin. A negative result does not preclude MRSA/SA (*Staphylococcus aureus)* nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further	The BD GeneOhm® MRSA ACP Assay is a qualitative *in vitro* diagnostic test for the direct detection of methicillin-resistant Staphylococcus aureus (MRSA) DNA from nasal swabs in patients at risk for nasal colonization. The test utilizes polymerase chain reaction (PCR) for the amplification of MRSA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified DNA. The BD GeneOhm® MRSA ACP Assay is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose MRSA infections nor to guide or monitor treatment for MRSA

	ELITech Molecular Diagnostics Device MRSA/SA ELITe MBG®	Predicate device BD GENEOHM MRSA ACP ASSAY (K093346)
	susceptibility testing.	infections. Concomitant cultures are necessary only to recover organisms for epidemiological typing or for further susceptibility testing.
Indication for Use	MRSA/SA ELITe MGB® is a qualitative in vitro diagnostic test for the direct detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) using DNA purified from nasal swabs. MRSA/SA ELITe MGB® is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose, guide or monitor MRSA infections, or provide results of susceptibility to oxacillin/methicillin. A negative result does not preclude MRSA/SA (*Staphylococcus aureus)* nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.	The BD GeneOhm® MRSA ACP Assay is a qualitative *in vitro* diagnostic test for the direct detection of methicillin-resistant Staphylococcus aureus (MRSA) DNA from nasal swabs in patients at risk for nasal colonization. The test utilizes polymerase chain reaction (PCR) for the amplification of MRSA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified DNA. The BD GeneOhm® MRSA ACP Assay is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose MRSA infections nor to guide or monitor treatment for MRSA infections. Concomitant cultures are necessary only to recover organisms for epidemiological typing or for further susceptibility testing.
Mode of identification of *S. aureus*	Presence of conserved region in a *Staphylococcus aureus*-specific gene.	Presence of SCC*mec* cassette (genetic element that carries the *mecA* gene) at *orfX* junction (specific to *S. aureus*)
Mode of detection for methicillin resistance	Presence of the *mecA* gene which is responsible for resistance to methicillin.	
Assay Format	Qualitative real-time polymerase chain reaction (PCR) assay using 3 forward primer, 3 reverse primers, and 3 fluorescent-labeled probes for the amplification and detection of methicillin resistant *Staphylococcus aureus* (MRSA) DNA.	Qualitative real-time polymerase chain reaction (PCR) assay using 1 forward primer, 5 reverse primers, and 2 molecular beacon probes for the amplification and detection of methicillin resistant *Staphylococcus aureus* (MRSA) DNA.
Composition	**MRSA/SA ELITe MGB® PCR Mix** Tfi PCR Master Mix <0.01% MRSA/SA primers <0.01% Internal Control primers <0.01% MRSA/SA Fluorescent-labeled oligonucleotide probes <0.01% Internal Control Fluorescent-labeled oligonucleotide probe <0.01% Fluorescent Passive	**Master Mix** < 0.0005% DNA polymerase complex < 0.001% Internal Control: non-infectious DNA containing MRSA-primer binding sequences and a unique sequence for probe hybridization < 0.06% primers < 0.02% Molecular beacon probes

	ELITech Molecular Diagnostics Device MRSA/SA ELITe MBG®	Predicate device BD GENEOHM MRSA ACP ASSAY (K093346)
	Reference dT(8)-AP593 **MRSA/SA Internal Control** Tris buffer <0.01% EDTA 0.01% total yeast RNA <0.001% Non-infectious plasmid DNA (recombinant) containing Internal Control sequences **MRSA/SA Positive Control** Tris buffer <0.01% EDTA 0.01% total yeast RNA <0.001% Non-infectious plasmid DNA (microbial) containing MRSA sequences	< 1% Nucleotide mix (dATP, dCTP, dGTP, dTTP) Bovine serum albumin Carbohydrate MgCl2 < 0.001% non-infectious Staphylococcus epidermidis genomic DNA (ATCC 14990) **Control DNA** Tris-EDTA buffer Carbohydrate < 0.001% non-infectious genomic MRSA DNA (ATCC 43300) **Diluent** Tris-HCl buffer MgCl2 (NH4)2SO4 KCl Tween-20
Appearance of reagents	Frozen, ready to use	Liquid, ready to use.
Sample type	Nasal swab	Nasal swab
Storage & Expiry	Stored in -20 °C freezer. The device is stable until the expiry date stated on the label.	Stored at 2- 25 °C. Reagents are stable until the expiry date stated on the label.
Instrument	ABI 7500 Fast Dx	BD SmartCycler® II
Controls	Positive PCR control (Plasmid DNA (microbial) containing MRSA sequences) Internal Control (Plasmid DNA (recombinant) containing Internal Control sequences)	Positive PCR control (DNA from S. aureus ATCC 43300). Negative PCR control (DNA from S. epidermidis ATCC 14990). Internal procedural control

Standard/Guidance Document Referenced

FDA Draft Guidance for Industry and Food and Drug Administration Staff Establishing the Performance Characteristics of Nucleic Acid-Based In vitro Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA), Issued January 5, 2011.

FDA Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices, Issued September 9, 1999.

Instrumentation/Software:

The system is performed with FDA-cleared devices, bioMérieux NucliSENS® easyMAG® extraction system and the Applied Biosystems® 7500 Fast Dx PCR Instrument. ELITechGroup Epoch Biosciences has a relationship with each on the manufacturers of these devices via service contracts such that Epoch will become aware, in the same time, as other users of the system, of changes to the device(s) or of the software used by the device(s). Internal quality assurance procedures are in place to verify the continued acceptable performance of the test device. Please, note, however, that the evaluation algorithm and the use of controls as indicated in the labeling, Internal Control and Positive Control, Negative Specimen Processing Control and Positive Specimen Processing Control, should identify for users any issues created by instrument or software changes.

Performance Characteristics

Interfering substances

A study was conducted with potentially interfering substances encountered on nasal swabs. Substances tests were chemical substances that can either be naturally present in the nasal cavity or that can be artificially introduced into the nasal cavity.

The following substances were tested and evaluated: blood, mucin, phenylephrine (Neo-synephrine®), oxymetazoline (Dristan®, Zicam®), sodium chloride with preservatives, benzalkonium chloride, sodium phosphate, phenylcarbinol (Saline), propylene glycol (AYR® saline nasal gel), sorbitol, benzyl alcohol, disodium EDTA, hypromellose, phosphoric acid, dexamethasone, triamcinolone (Nasacort®), beclomethasone (Beconase AQ®), flunisolide, budesonide (Rhinocort Aqua®), mometasone (Nasonex®), fluticasone (Flonase®), luffa opperculata, sulfur, Galphimia glauca, Histaminum hydrochloricum, live intranasal influenza virus vaccine (FluMist®), benzocaine, methol (Cepacol® sore throat lozenges), Zanamivir (Relenza®), Oseltamivir phosphate (Tamiflu©), Mupirocin, tobramycin.

The following substances have been shown to interfere with the performance of the assay: AYR® saline nasal gel and excessive amounts of nasal secretions/mucus.

Non-Clinical Performance Evaluation

A. Analytical Sensitivity

The analytical sensitivity of the MRSA/SA ELITe MGB® was determined using 5 strains of MRSA and one MSSA strain. Cultures of these strains were quantified, diluted in simulated nasal matrix to values spanning the range of approximately 5 to 1500 colonies forming units (CFU) and absorbed onto swabs. All dilutions were tested, and the limit of detection (LoD) was determined by Probit analysis. LoD for each strain represents the lowest number of CFU/swab at which a positive result will be obtained with at least 95% confidence. LoD for each strain was then verified by testing at least 20 replicates. Results indicate that the MRSA/SA ELITe MGB® average LoD is 165 CFU/mL of a swab eluate.

B. Analytical Reactivity

Inclusivity

Performance of the MRSA/SA ELITe MGB® was tested on 75 well characterized MRSA and MSSA isolates representative of the global genetic diversity, including clonal complexes and sequence types as well as various Pulse-Field Gel Electrophoresis (PFGE) types and MIC (Minimum Inhibitory Concentration) values, with the emphasis on the USA epidemiologic clones. The strains were obtained through the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) Program and from American Tissue Culture Collection (ATCC) or were a gift from Medical College of Wisconsin[1]. All strains were absorbed onto swabs at near detection limit and tested with MRSA/SA ELITe MGB®. In addition to that all

[1] Gift from Dr. Nathan A. Ledeboer, Medical College of Wisconsin, WI; the strains are described in: Buchan, B.W, Ledeboer, N.A. Identification of Two Borderline Oxacillin-Resistant Strains of Staphylococcus aureus From Routine Nares Swab Specimens by One of Three Chromogenic Agars Evaluated for the Detection of MRSA, Microbiology and Infectious Disease.2010:134;921-927.

MSSA strains were tested at 10^6CFU/swab. All MSSA strains tested positive for SA and negative for MRSA. All MRSA strains tested positive for MRSA. Two BORSA (Borderline Oxacillin Resistant *Staphylococcus aureus*) isolates that lack mecA[19] tested SA positive and MRSA negative for an overall analytical reactivity of 97.3%.

C. Analytical Specificity

Exclusivity

The specificity of the MRSA/SA ELITe MGB® was evaluated by testing for cross-reactivity to species phylogenetically related to *S. aureus*, pathogenic microorganisms and to microorganisms commonly present in normal nasal microflora. The test panel consisted of 17 viral, 3 fungal, 1 mycoplasma, and 41 bacterial species. The microorganisms were tested as cultures in concentrations of $1x10^6$ CFU ($1x10^5$ PFU)/swab. In addition human cells in a concentration of 10^6 cells /mL were tested. Human cells and all tested species were found negative for MRSA and SA with the MRSA/SA ELITe MGB®. The analytical specificity was 100%.

Species Tested for Cross-Reactivity and Microbial Interference

***Staphylococci* Species**	**Other Organisms**	**Viruses**
CoNS* *Staphylococcus arlettae,* *Staphylococcus capitis,* *Staphylococcus carnosus,* *Staphylococcus chromogenes,* *Staphylococcus equorum,* *Staphylococcus felis,* *Staphylococcus gallinarum,* *Staphylococcus hominis subsp. hominis,* *Staphylococcus kloosii,* *Staphylococcus lentus,* *Staphylococcus pulvereri,* *Staphylococcus simulans,* *Staphylococcus warneri* **MSCoPS*** *Staphylococcus delphini,* **MSCoNS*** *Staphylococcus epidermidis,* *Staphylococcus xylosus* **MRCoNS*** *Staphylococcus epidermidis* **CoPS*** *Staphylococcus hyicus,* *Staphylococcus intermedius*	*Acinetobacter haemolyticus, Bacillus cereus, Bordetella pertussis, Citrobacter freundii, Citrobacter koseri, Corynebacterium aquaticum, Corynebacterium bovis, Corynebacterium flavescens, Corynebacterium genitalium, Enterobacter aerogenes, Enterococcus faecalis, Enterococcus faecium, Enterococcus flavescens, Enterococcus gallinarum, Enterococcus hiraem, Escherichia coli, ESBL producer, Klebsiella oxytoca, Klebsiella pneumoniae, ESBL producer, Listeria monocytogenes, Moraxella catarrhalis, Pasteurella aerogenes, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Salmonella typhimurium, Serratia marcescens, Shigella sonnei, Streptococcus mitis, Streptococcus salivarius, Yersinia enterocolitica, Candida albicans, Candida glabrata, Cryptococcus neoformans, Lactobacillus acidophilus, Legionella pneumophila, Mycobacterium tuberculosis avirulent, Mycoplasma pneumoniae, Neisseria meningitides, Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes, Homo sapiens, Human Cells* HT1080	*Adenovirus Type 1,* *Adenovirus Type 7A,* *Human coronavirus (229E),* *Human coronavirus (OC43),* *Cytomegalovirus,* *Coxsackievirus Type A21,* *Epstein Barr Virus,* *Human influenza virus A,* *Human influenza virus B,* *Human parainfluenza Type 2,* *Human parainfluenza Type 3,* *Human metapneumovirus 3 Type B1,* *Measles,* *Mumps virus,* *Respiratory syncytial virus Type B,* *Rhinovirus Type 1A*

* **CoNS:** coagulase-negative *Staphylococci*,
MSCoPS: methicillin susceptible coagulase positive *Staphylococci*,
MSCoNS: methicillin susceptible coagulase negative *Staphylococci*,

MRCoNS: methicillin resistant coagulase negative *Staphylococci*,
CoPS: coagulase positive *Staphylococci*

Two of the potentially interfering organisms tested, *Human metapneumovirus* (hMPV) and MRCoNS *Staphylococcus epidermidis,* strain NRS 34, caused interference at initial test.

Re-testing of MRCoNS *Staphylococcus epidermidis,* strain NRS 34 confirmed the interference results. MRCoNS *Staphylococcus epidermidis,* strain NRS 34, is considered to interfere with MRSA/SA ELITe MGB®.

- MRCoNS *Staphylococcus epidermidis* when tested in a mix with near-detection-limit -MRSA resulted in "SA positive, MRSA negative" call.

Re-testing of *Human metapneumovirus* (hMPV) did not reveal interference of hMPV with MRSA/SA ELITe MGB®.

Methicillin Susceptible S. aureus (MSSA) was also tested for microbial interference. The microorganism was spiked at 1×10^6 CFU/mL (1×10^5 PFU/mL), or higher, into a sample with MRSA strains at near-detection-limit and tested.

- MRCoNS Staphylococcus epidermidis and MSSA, when tested in a mix with near-detection-limit of MRSA, resulted in "SA positive, MRSA negative" call.

None of the other tested species interfered with MRSA/SA detection.

D. Reproducibility

A 10-member panel of specimens with varying concentrations of MRSA and MSSA in a simulated nasal matrix was tested. Two MRSA strains (ATCC BAA-1556 and BAA-1720) and one MSSA strain (BAA-12600) were used. Simulated matrix contained human genomic DNA and mucin to imitate a normal human nasal matrix. Data from the specimens were pooled to produce four sample types:
For each MRSA/MSSA strain the panel included a negative member, specimen below the LoD (expected to yield a positivity rate of between 20 to 80%), low positive (at LoD, expected to yield a 95% positivity rate), and moderate positive (three times LoD, expected to have 100% positivity rate).

Each of the two operators performed one run per day for 12 days on three reagent lots at one site. In two other sites two runs per day on one reagent lot were performed for 5 days (10 specimens x 3 replicates x 5 days x 2 runs).

The negative panel member yielded negative results 100%, the below LoD specimens positivity rate was 77%, the low positive specimen positivity rate was 98%, and the moderate positive panel members positivity rate was 100%.

Cumulative data of reproducibility study

Specimen Type	Lot 1	Lot 2	Lot 3	Total Agreement (%)
Negative (R1)	14/14	14/14	30/30	58/58 (100%)
Below LoD (R2,R5,R8)	33/42	31/42	70/90	134/174 (77%)
Low Positive (R3,R6,R9)	40/42	42/42	88/90	170/174 (98%)
Moderate Positive (R4,R7,R10)	42/42	42/42	90/90	174/174 (100%)

The numerical results based on Ct values follow:

Cumulative data of reproducibility study

Idh1

Panel #	N	Mean Ct	Within-Run		Between-Run		Between-Day		Between-Operator		Between-Lot		Between-System		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
R1	118	38.12	NA1	NA1	0.67	1.75	0.45	1.18	0.29	0.76	0.39	1.03	0.15	0.40	0.39	1.02
R2	118	36.22	0.65	1.79	0.99	2.74	0.79	2.18	0.82	2.26	0.32	0.89	0.86	2.38	0.74	2.04
R3	118	35.39	0.62	1.73	0.96	2.72	0.86	2.42	0.94	2.65	0.43	1.23	1.08	3.06	0.82	2.30
R4	118	34.35	0.41	1.20	0.67	1.94	0.53	1.54	0.42	1.22	0.48	1.40	0.35	1.03	0.48	1.39
R5	118	36.73	0.71	1.94	0.87	2.37	0.79	2.16	0.56	1.52	0.50	1.37	0.45	1.23	0.65	1.77
R6	118	33.66	0.42	1.24	0.69	2.05	0.64	1.92	0.56	1.66	0.48	1.44	0.58	1.72	0.56	1.67
R7	118	31.81	0.17	0.54	0.76	2.38	0.67	2.09	0.73	2.28	0.43	1.36	0.83	2.60	0.60	1.88
R8	118	37.68	0.77	2.05	0.74	1.97	0.43	1.15	0.39	1.03	0.12	0.33	0.40	1.06	0.48	1.26
R9	118	34.65	0.56	1.60	0.64	1.84	0.51	1.49	0.54	1.56	0.08	0.23	0.60	1.74	0.49	1.41
R10	118	32.82	0.58	1.76	0.48	1.45	0.42	1.28	0.37	1.13	0.17	0.53	0.40	1.21	0.40	1.23
PSPC	44	34.25	NA2	NA2	0.71	2.08	0.41	1.21	0.41	1.18	0.18	0.52	0.59	1.72	0.46	1.34
PC	44	28.12	NA2	NA2	1.08	3.86	1.18	4.20	0.58	2.07	1.21	4.24	0.50	1.79	0.91	3.23
NSPC	44	38.24	NA2	NA2	0.63	1.64	0.65	1.69	0.85	2.24	0.11	0.30	0.82	2.15	0.61	1.60
NTC	44	38.14	NA2	NA2	NA3	NA3	NA3	NA3	NA3	NA3	NA3	NA3	NA3	NA3	NA3	NA3

mecA

Panel #	N	Mean Ct	Within-Run		Between-Run		Between-Day		Between-Operator		Between-Lot		Between-System		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
R1	118	38.53	NA1	NA1	1.08	2.81	1.31	3.42	0.76	1.97	0.97	2.54	0.32	0.83	0.89	2.31
R2	118	36.87	0.53	1.43	0.93	2.52	0.68	1.84	0.68	1.85	0.40	1.09	0.74	2.02	0.66	1.79
R3	118	36.40	0.59	1.62	1.13	3.12	0.99	2.73	1.15	3.15	0.66	1.83	1.27	3.51	0.97	2.66
R4	118	35.17	0.37	1.05	0.68	1.94	0.54	1.54	0.46	1.32	0.43	1.24	0.41	1.17	0.48	1.38
R5	118	37.31	0.60	1.62	0.64	1.71	0.50	1.35	0.44	1.17	0.47	1.26	0.46	1.24	0.52	1.39
R6	118	34.45	0.43	1.24	0.74	2.15	0.70	2.04	0.58	1.68	0.61	1.78	0.60	1.74	0.61	1.77
R7	118	32.50	0.19	0.58	0.87	2.68	0.76	2.34	0.85	2.61	0.52	1.61	0.95	2.91	0.69	2.12
R8	118	39.12	NA4	NA4	0.55	1.42	0.52	1.35	0.45	1.16	0.25	0.65	0.33	0.86	0.42	1.09
R9	118	38.83	NA4	NA4	0.62	1.59	0.46	1.17	0.38	0.97	0.14	0.35	0.32	0.83	0.38	0.98
R10	118	38.74	NA4	NA4	0.77	1.98	0.57	1.46	0.40	1.05	0.36	0.94	0.31	0.79	0.48	1.25
PSPC	44	35.03	NA2	NA2	0.73	2.08	0.56	1.60	0.42	1.20	0.28	0.80	0.56	1.60	0.51	1.45
PC	44	29.18	NA2	NA2	1.11	3.82	1.23	4.21	0.51	1.74	1.24	4.22	0.40	1.37	0.90	3.07
NSPC	44	39.03	NA2	NA2	0.48	1.22	0.48	1.22	0.48	1.22	0.58	1.48	NA5	NA5	0.50	1.28
NTC	44	39.53	NA2	NA2	0.24	0.61	0.24	0.61	0.24	0.61	NA6	NA6	0.24	0.61	0.24	0.61

IC2

Panel #	N	Mean Ct	Within-Run		Between-Run		Between-Day		Between-Operator		Between-Lot		Between-System		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
R1	118	30.26	0.15	0.50	0.27	0.89	0.17	0.55	0.18	0.59	0.05	0.18	0.23	0.75	0.17	0.58
R2	118	30.24	0.18	0.58	0.30	1.00	0.24	0.79	0.18	0.60	0.03	0.10	0.24	0.78	0.19	0.64
R3	118	30.30	0.17	0.57	0.25	0.81	0.18	0.60	0.17	0.57	0.04	0.14	0.20	0.66	0.17	0.56
R4	118	30.26	0.12	0.39	0.27	0.88	0.16	0.53	0.17	0.57	0.11	0.36	0.18	0.58	0.17	0.55
R5	118	30.23	0.22	0.72	0.33	1.09	0.24	0.78	0.23	0.75	0.10	0.34	0.27	0.88	0.23	0.76
R6	118	30.38	0.22	0.74	0.43	1.40	0.31	1.01	0.14	0.47	0.06	0.20	0.09	0.30	0.21	0.69
R7	118	30.31	0.15	0.50	0.30	0.98	0.21	0.68	0.13	0.42	0.04	0.12	0.14	0.45	0.16	0.53
R8	118	30.39	0.23	0.76	0.38	1.24	0.24	0.79	0.25	0.81	0.21	0.68	0.20	0.66	0.25	0.82
R9	118	30.34	0.14	0.46	0.32	1.06	0.23	0.74	0.28	0.93	0.12	0.38	0.26	0.87	0.23	0.74
R10	118	30.16	0.24	0.80	0.51	1.70	0.27	0.89	0.31	1.04	0.13	0.42	0.33	1.09	0.30	0.99
PSPC	44	30.26	NA2	NA2	0.47	1.55	0.36	1.18	0.32	1.05	0.33	1.09	0.28	0.94	0.35	1.16
PC	44	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7
NSPC	44	30.27	NA2	NA2	0.63	2.09	0.51	1.68	0.48	1.59	0.35	1.15	0.32	1.05	0.46	1.51
NTC	44	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7	NA7

NA1: For R1 (Negative Samples) only in a few runs, just one sample in triplicates shown a weak signal in ldh channel. Therefore, calculations of within-run SD and %CV for these (R1) samples were not possible.

NA2: For the Controls (PSPC, PC, NSPC, NTC), just one replicate was used for each run. Therefore, it was impossible to calculate within-run SD and %CV for these samples. See between-run values instead

NA3: In NTCs, there was only one single observation of ldh1 detection throughout the study. Therefore, SD & %CV calculations were not possible for this category of samples.

NA4: In R8-R10 samples (MSSA), due to none or rare (one per triplicate) occurrence of mecA signal detection it was not possible to calculate SD & %CV for this target.

NA5: For NSPC samples, only testing with one System (Instrument-Site) gave a positive signal in mecA channel. Therefore, SD & %CV calculations are not possible for this category of samples.

NA6: For NTC samples, only testing with one Lot gave a positive signal in mecA channel. Therefore, SD & %CV calculations are impossible for this category of samples.

NA7: Internal Control (IC2) was not added to Positive (PC) and Negative (NTC) amplification controls.

E. Carry-Over / Cross-Contamination

An analytical study was performed to evaluate the potential for cross-contamination between high MRSA (1×10^7 CFU per mL) specimens and negative specimens throughout the MRSA/SA ELITe MGB® workflow. Two operators performed five 24-sample extraction runs (11 high MRSA samples, 11 negative samples, 1 PSPC sample, and 1 NSPC sample per run) in a checkerboard pattern (high MRSA samples interrupted by completely negative samples). The processed samples were then PCR amplified in five separate runs using two different checkerboard patterns. The cross-contamination testing resulted in zero false negatives from fifty-five high MRSA positive samples and one false positive sample from fifty-five negative samples.

Clinical Performance

Performance characteristics of the MRSA/SA ELITe MGB® were determined in a prospective investigational study at three (3) sites by comparing the MRSA/SA ELITe MGB® with agglutination/susceptibility tests. Specimens were collected from three (3) unique geographies at institutions having MRSA culture-based screening programs in place. To be enrolled in the study, patients had to be eligible for MRSA screening according to the policies of the respective facilities. A true MRSA culture-positive specimen was defined as a specimen where MRSA was identified by the latex agglutination and cefoxitin susceptibility test after broth enrichment (both positive). A true MSSA culture-positive specimen was defined as a specimen negative for cefoxitin susceptibility testing and positive for the latex agglutination test.

One nasal swab was collected from each patient and used to inoculate a selective chromogenic MRSA screening agar plate. Then the swab was inserted into a tube with trypticase soy broth and thoroughly mixed. The entire volume of the cell suspension was tested using MRSA/SA ELITe MGB. All swabs were subjected to enrichment in trypticase soy broth with 6.5% NaCl. The enriched culture samples were inoculated onto Trypticase Soy Blood Agar plates. Grown overnight cultures were used for latex agglutination. Specimens positive for latex agglutination were used for the cefoxitin susceptibility test.

Performance of the MRSA/SA ELITe MGB® was calculated relative to the broth culture followed by latex agglutination and cefoxitin susceptibility test results.

A total of 3271 nasal swab specimens were collected and tested. Of the 3271 specimen tested, 3174 specimens were eligible to be included in statistical analyses: 72 specimens were considered to be ineligible due to a duplicating error during samples collection and preparation; 21 specimens failed the initial extraction due to an operator error. Those samples were retested from the original swabs. 25 specimens failed the extraction and have been removed from the study.

Compared to the reference culture method, MRSA/SA ELITe MGB® identified 92% of the specimens testing positive for MRSA and 95% of the negative specimens.

Compared to the reference culture method, MRSA/SA ELITe MGB® identified 96% of the specimens testing positive for SA and 95% of the negative specimens.

Summarized (for all data combined) MRSA/SA ELITe MGB® performance table[2]:

Combined Data		Reference Culture			
		MRSA+	SA+/MRSA-	Neg/No Growth	Total
MRSA/SA ELITe MGB®	MRSA+	**205**	**111**	**32**	**348**
	SA+/MRSA-	**17**	**405**	**86**	**508**
	SA-	**0**	**30**	**2288**	**2318**
	Total	**222**	**546**	**2406**	**3174**
	MRSA: Sensitivity: 92.3% (88.08%-95.16%) Specificity: 95.2% (94.32%-95.87%) PPV: 58.9% (53.67%-63.95%) NPV: 99.4% (99.04%-99.62%) **SA:** Sensitivity: 96.1% (94.48%-97.25%) Specificity: 95.1% (94.16%-95.89%) PPV: 86.2% (83.74%-88.36%) NPV: 98.7% (98.16%-99.09%) Note: The statistics shown are the calculated values with the 95% confidence interval in the parentheses.				

[2] Discrepant Analysis: Further investigation (testing for MRSA by sequencing of SCCmec right extremity junction) was performed on all specimens that gave discordant MRSA results between the reference culture method and MRSA/SA ELITe MGB™.

- 16 of the 17 specimens that were MRSA-positive by culture but MRSA-negative by MRSA/SA ELITe MGB™ were found to be MRSA positive by SCCmec right extremity junction sequencing.
- 22 of the 143 specimens that were MRSA-negative by culture but MRSA-positive by MRSA/SA ELITe MGB™ were found to be MRSA positive by SCCmec right extremity junction sequencing.

Compared to the culture method of reference(agglutination/cefoxitin testing), the MRSA/SA ELITe MGB™ identified ~93% of the specimens positive for MRSA by a reference method and ~96% of the MRSA-negative specimens.

PPV: 65.2% (60.08%, 70.04%), NPV: 99.4% (99.08%, 99.65%)

Thus, the positive and negative agreements for MRSA were each increased by 1% to achieve 93% and 96% respectively. Positive Predictive Value for MRSA was also increased by 6% to achieve 65%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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C/o Debra K. Hutson
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21720 23rd Drive SE, Suite 150
Bothell, WA 98021

JUN - 1 2012

Re: k112937
Trade/Device Name: MRSA/SA ELITe MGB®
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: NQX
Dated: May 9, 2012
Received: May 11, 2012

Dear Ms. Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _K112937_____

Device Name: _____ MRSA/SA ELITe MGB® _____

Indications for Use:

MRSA/SA ELITe MGB® is a qualitative *in vitro* diagnostic test for the direct detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) using DNA purified from nasal swabs. MRSA/SA ELITe MGB® is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose, guide or monitor MRSA infections, or provide results of susceptibility to oxacillin/methicillin. A negative result does not preclude MRSA/SA (*Staphylococcus aureus*) nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Freddie Tu Padie

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112937